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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,344	07/06/2001	Muneo Tokita	482842000300	8523

7590 10/08/2003

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,344

Applicant(s)

TOKITA ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,12-15,17-25 and 28-36 is/are rejected.
- 7) ☒ Claim(s) 3,8-11,16,26 and 27 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 recites the limitation "said predetermined orientation" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

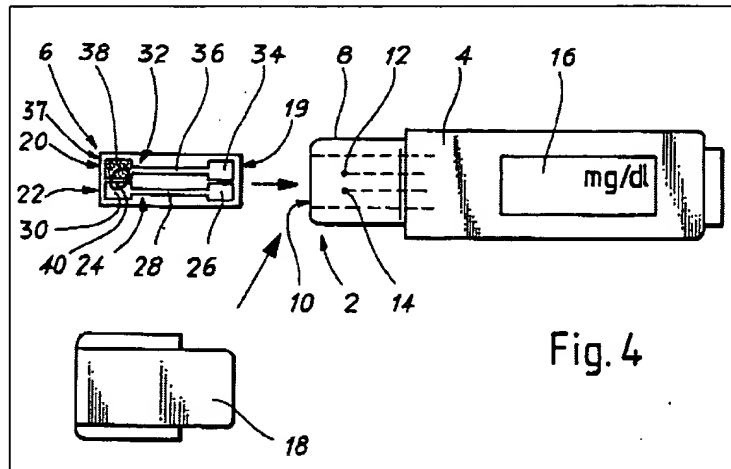
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 – 7, 12 – 15, 19 – 22, 29 – 32, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Grätzel *et al.* (U.S. Pat. No. 5,378,628 A). Regarding claims 1, 29 – 32 and 35, Grätzel *et al.* teach an apparatus comprising: a sensor pack (sensor 6) comprising a sensor chip (collector 37) having a reaction portion (two electrodes 20 & 22) for reacting with a test sample (sample drop 40); and an analyzer device (pen 4) having an opening (cavity 10) for accepting the sensor pack containing one sensor chip, and retaining means (extremity portion 8 & cavity 10) for retaining the sensor chip in the sensor pack accepted through the opening, wherein the analyzer device analyzes an ingredient in a test sample

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supplied to the reaction portion by detecting a change in the reaction portion (see col. 4, lines 35 – 68; col. 5, lines 1 – 65; figure 4).



Regarding the recitation that the “ sensor pack is formed by packing in a packaging material a sensor chip ... ,” this claim is attempting to define the product by defining the process by which the product is made in terms of a product-by-process claim. The applicant is advised that even though product-by-process claims are limited by and defined by the process, determination of patentability is based upon the product itself. The patentability of a product does not depend upon its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113). Regarding claim 2, Grätzel *et al.* teach that the sensor chip has an engagement means (extremity portion 19) for engagement with the retaining means (extremity portion 8 & cavity 10) (see figure 4). Regarding claim 4, it is inherently anticipated that the sensor pack (6) has a holding, such as an edge, to be held by the user (see figure 4). Regarding claims 5 and 31, it is inherently anticipated sensor pack (6) has a

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positioning means, such as side edges, for positioning the sensor chip (37) within the opening (10) of the analyzer device (4) (see figure 4). Regarding claim 6, the analyzing device (4) has a positioning means, such as the side edges of the opening (cavity 10), for positioning the sensor chip (37) when only the sensor chip is inserted through the opening (see figure 4). Regarding claim 7, it is inherently anticipated that the retention means (extremity portion 8 & cavity 10) of the analyzing device (4) can be effectively disengaged in order to remove the sensor chip (37) after use (see figure 4). Regarding claims 12 and 15, the analyzing device (4) further comprises a reaction information acquisition means (two first electrical contacts 12 & 14 connected to an ammeter) provided within the retaining means (cavity 10) for obtaining information on the reaction at the reaction portion of the sensor chip (see col. 4, lines 35 – 51; figure 4). Regarding claims 19, 22, 35 and 36, Grätzel *et al.* teach that a predetermined orientation of the sensor pack (6) with respect to the direction of insertion into the opening (10) of the analyzing device (4) is prescribed, wherein a cross-sectional shape of the sensor pack as viewed in the direction of insertion when the sensor pack has an orientation different from the predetermined orientation, which is different from the cross-sectional shape of the opening as viewed in the direction of insertion (see figure 4). Regarding claims 20 and 21, Grätzel *et al.* further teach that the sensor chip (37) has the shape of a generally flat block, wherein the sensor pack (6) and the opening (10) has a shape exhibiting an asymmetry on the opposite sides of the two surfaces of the sensor chip (see figure 4).

Regarding claims 13, 14 and 32, it should be noted that these claims are directed to a system or an apparatus. Therefore, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus. These claims

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recite various process or use limitations and are accorded no patentable weight to an apparatus. For example, these claims recite how the apparatus is to be operated, such as by removing a packaging material portion during use, which do not impart any limitations to define the structure of the apparatus being claimed. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 18, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* in view of Crosby (U.S. Pat. No. 6,217,744 B1). Regarding claims 17 and 33, Grätzel *et al.* do not specifically teach the incorporation of a desiccant with the sensor pack. Grätzel *et al.* do teach that the sensor is dried prior to use (see col. 6, lines 32 – 41). Crosby does teach a biological fluid testing apparatus packaged with a desiccant material, such as silica gel, to prevent the inadvertent early activation of the detection system by exposure to fluid (see col. 6, lines 53 – 56). Hence, Crosby recognizes the suitability of incorporating a desiccant material with a biological fluid testing apparatus in order to preserve the function of the apparatus prior to use (see MPEP § 2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a desiccant material, as taught by Crosby, with the sensor pack of the apparatus, as taught by Grätzel *et al.*, in order to maintain the function of the sensing apparatus prior to use. Regarding claims 18 and 34, the sensor pack (6) comprises a holding feature, such as side edges, for facilitating the holding of the sensor pack by a user. It would have been obvious to one of ordinary skill in the art to incorporate an accommodation portion with the sensor pack for containing the desiccant material so as to facilitate the effective functional preservation of the apparatus prior to use.

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Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* in view of Baker *et al.* (U.S. Pat. No. 4,654,127). Regarding claim 23, Grätzel *et al.* do not specifically teach the further incorporation of an inserted state detection means for detecting an insertion state of the sensor pack having a detecting portion provided in the analyzing device and a portion to be detected provided in the sensor pack at a predetermined position. However, Baker *et al.* do teach an analysis apparatus (14) that involves the insertion of a test device (12) into a receptacle (62) of the analysis apparatus (14). Baker *et al.* teach that the insertion of the device (12) into receptacle (62) causes the bar code on the bottom of the device (12) to be read by a latent detection means and connects contacts (32A-32E) to analyzer (14) (see col. 9, lines 36 – 40; figure 1). Hence, Baker *et al.* recognize the suitability of incorporating a reading or detection means for an analysis apparatus using a test card or sensing chip analysis format in order to facilitate effective apparatus operation and sample analysis (see MPEP § 2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the reading or detection means, as taught by Baker *et al.*, with the sensing apparatus, as taught by Grätzel *et al.*, in order to facilitate effective apparatus operation and sample analysis. Regarding claim 25, Grätzel *et al.* do not specifically teach the further incorporation of an information holding means for holding information on the sensor chip, wherein the information holding means is provided on at least one of either the sensor pack or sensor chip; and an information recognition means for recognizing information held by the information holding means, wherein the information recognition means is provided on the analyzing device. However, Baker *et al.* do teach that the testing device (12 & 16) incorporates the use of a bar code (47), which provides specific information on performing a specific analysis for the analyzer (14) upon

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insertion of the device (see col. 4, line 49 – col. 5, line 64; figure 8). Hence, Baker *et al.* recognize the suitability of incorporating a bar code or information holding means with an insertable test device for an analysis apparatus using a test card or sensing chip analysis format in order to facilitate effective apparatus operation and sample analysis (see MPEP § 2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the use of a bar code or information holding means, as taught by, Baker *et al.*, with an analysis apparatus, as taught by Grätzel *et al.*, in order to facilitate effective apparatus operation and sample analysis.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* in view of Lape (U.S. Pat. No. 4,661,319). Grätzel *et al.* do not specifically teach the further incorporation of a speech generation means within the analyzing device. Grätzel *et al.* do teach that the apparatus is used for the personal detection of blood glucose level, wherein the blood glucose level is indicated by a display (16) (see col. 4, lines 1 – 56; figure 4). Lape teaches a blood glucose testing apparatus that uses a speech generation means to indicate the blood glucose concentration as read by the blood glucose monitor (see col. 7, lines 31 – 63). Therefore, the prior art, as evidenced by Lape, recognizes the suitability of incorporating the use of a speech generation means with a blood glucose monitoring apparatus for the intended purpose of facilitating the effective notification of a blood glucose test result to a user (see MPEP section 2144.07). Both of these indication techniques, the use of a display or speech generation means, as evidenced by Grätzel *et al.* and Lape, respectively, are notoriously well known in the art for being utilized for the same purpose, for indicating blood glucose test results.

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Hence, these indication techniques are considered functional equivalents clearly recognized in the prior art (see MPEP section 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to one of ordinary skill in the art to substitute and incorporate the known equivalent indication technique of using a speech generation means, as taught by Lape, with the analytical detection system, as taught by Grätzel *et al.*, in order to facilitate effective test result notification to the user.

Allowable Subject Matter

Claims 3, 8 – 11, 16 and 26 – 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art neither teach or fairly suggest the further incorporation of a retaining means, which penetrates the packaging material at least to reach the sensor chip. The cited prior art neither teach or fairly suggest the further incorporation of a state changing means within the analyzing device for changing the state of the retaining means between a state of receding from the sensor pack and a state of retaining the sensor chip, wherein the state changing means changes the state of the retaining means so that the retaining means is in the receding state when

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the sensor pack is inserted and so that the retaining means is in the retaining state after the completion of insertion of the sensor pack. The cited prior art neither teach or fairly suggest that the analyzing device further incorporates a first reaction information acquisition means for obtaining information on the reaction at the reaction portions of the sensor chip when the sensor chip is inserted in the state of having a predetermined orientation to the opening; and a second reaction information acquisition means for obtaining information on the reaction at the reaction portion on the sensor chip when the sensor chip is inserted in the opening in the state of having an orientation different from the predetermined orientation. The cited prior art neither teach or fairly suggest the further incorporation within the analyzing device an opening forming means for forming an opening in the packaging material of the sensor pack.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Douglas *et al.* teach an analyte detection system using test strips. Flaherty *et al.* teach a multi-use electrochemical sensor package.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700